

**Curriculum Vitae**  
**Michael David Hughes**

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**Degrees**

1983 B.A. University of Cambridge, UK  
Part I: Mathematics  
Part II: Statistics & Operational Research  
(First Class Honours)

1984 M.Sc. London School of Hygiene and Tropical Medicine  
University of London, UK  
Medical Statistics  
(Awarded with distinction)

1990 Ph.D. Royal Free Hospital School of Medicine,  
University of London, UK  
Medical Statistics

**Academic Appointments**

2000 to present Professor  
Department of Biostatistics  
Harvard School of Public Health

1995 to 2000 Associate Professor  
Department of Biostatistics  
Harvard School of Public Health  
(including leave 1996 to 1997: Senior Lecturer  
London School of Hygiene and Tropical Medicine,  
University of London. UK)

1991 to 1995	Assistant Professor Department of Biostatistics Harvard School of Public Health
1989 to 1990	Lecturer in Medical Statistics London School of Hygiene and Tropical Medicine University of London, UK
1986 to 1989	Research Fellow & Honorary Lecturer (Medical Statistics) Royal Free Hospital School of Medicine University of London, UK
1985 to 1986	Research Associate (Statistics) University of Kent at Canterbury, UK

### **Other Professional Appointments**

2003 to present	Director, Statistical and Data Management Center NIAID Adult AIDS Clinical Trials Group Center for Biostatistics in AIDS Research Harvard School Public Health
1998 to 2003	Director, Statistical and Data Management Center NIAID Pediatric AIDS Clinical Trials Group Center for Biostatistics in AIDS Research Harvard School Public Health
1992 to 1996	Head, HIV Disease Section Statistical and Data Analysis Center NIAID AIDS Clinical Trials Group Center for Biostatistics in AIDS Research Harvard School of Public Health
1988 to 1990	Visiting Lecturer in Medical Statistics City University, London, UK
1988 to 1989	Visiting Lecturer in Medical Statistics Royal College of Radiologists, London, UK
1985	Teacher (Mathematics and Statistics to Scholarship level) Dover Grammar School, Dover, UK

## **Other Professional Service**

2003 to present	Member of Executive Committee NIAID Adult AIDS Clinical Trials Group
1998 to 2003	Member of Executive Committee NIAID Pediatric AIDS Clinical Trials Group
1994 to 1996	Member of the Human Subjects Institutional Review Board, Harvard School of Public Health
1992 to present	Statistician, Center for Pancreatic Disease Brigham and Women's Hospital, Boston
1992 to 1996	Member of HIV Disease Resource Allocation Committee NIAID AIDS Clinical Trials Group
1985 to 1986	Statistician UK DHSS-sponsored Domiciliary Care Project
1983	Leader and Statistician Cambridge Parasite Study Expedition to Bolivia

## **Clinical Trial Data and Safety Monitoring Boards**

2002 to present	SciClone Inc.
1998 to present	Biomira Inc.
1998 to 2002	Chiron Inc.
1998 to 1999	U.S. Bioscience
1996 to 1998	Boehringer Ingelheim Pharmaceuticals Inc.
1995 to 2000	American Foundation for AIDS Research
1995	Sandoz Pharmaceuticals Corporation
1986 to 1992	Dutch Government's CNSLD long-term clinical trials

## **Consultancies for Pharmaceutical Companies**

2002 to present	Bristol-Myers Quibb
2002	Roche. NJ
1998 to 2001	SmithKline Beecham. PA
1996 to 1997	Roche Pharmaceuticals. UK
1991 to 1993	Amarillo Cell Culture. Texas
1989 to 1990	Societe pour la Recherche Cardiologique, Switzerland
1986 to 1990	Synthelabo Recherche. London

## **Editorial Boards**

2002 to present	Statistical Editor, Journal of Infectious Diseases
1990 to present	Statistics in Medicine
1999 to present	Statistical Methods in Medical Research

## **Refereeing (1998 to present)**

Statistical: Applied Statistics, Biometrics, Controlled Clinical Trials, Journal of the American Statistical Association, Statistics in Medicine, Statistical Methods in Medical Research, Statistics and Probability Letters.

Clinical: AIDS, AIDS Research and Human Retroviruses, Antiviral Therapy, Journal of AIDS and Human Retroviruses, Journal of Alternative and Complementary Medicine, Journal of Infectious Diseases, Lancet, Journal of the American Medical Association, New England Journal of Medicine.

## **Professional Societies**

Member of the Biometric Society

Member of the American Statistical Association (Elected a Fellow of the Association, 2002)

Member of the Society for Clinical Trials

## **Major Research Interests**

Statistical methodology for the design and analysis of clinical trials, in particular in HIV research. Specific current interests include the evaluation of surrogate endpoints, design of phase I/II clinical trials with a special emphasis on "special populations" (e.g. children, pregnant women), and the design and analysis of studies using repeated left and right censored laboratory measurements.

## **Funding**

2003 to 2004	Statistical and Data Management Center for the Adult AIDS Clinical Trials Group (approx) per year from NIAID.
1998 to 2008	Statistical and Data Management Center for the Pediatric AIDS Clinical Trials Group (approx) per year from NIAID.

- 1999 to 2000      Meta-analysis of HIV-1 RNA data in AIDS clinical trials.  
                              — from Roche Inc.
- 1997 to 1998      HIV Surrogate Marker Collaborative Group's Meta-analysis Project  
                              — from Glaxo-Wellcome Inc.
- 1997                Statistical methods for repeated measures data in respiratory disease trials.  
                              — (approx) from Astra. Sweden.

### **Teaching Experience**

- 2003:                Harvard School of Public Health  
                              Biostatistics doctoral program  
                              Lecturer and course developer: Design of Scientific  
                              Investigations
- 2002:                Harvard School of Public Health  
                              Biostatistics doctoral program  
                              Lecturer and course developer: Nonparametric Statistical  
                              Methods
- 1999 to 2001:      Harvard School of Public Health  
                              Biostatistics doctoral program  
                              Lecturer and course developer: Methods II  
                              (includes discrete data analysis and survival analysis)
- 1996 to 1997:      London School of Hygiene and Tropical Medicine  
                              MSc Medical Statistics  
                              Lecturer and course developer: Probability and Inference  
                              Lecturer and course coordinator: Clinical Trials
- 1992 to 1996:      Harvard School of Public Health  
                              Postgraduate programs  
                              Lecturer and course developer: Clinical Trials
- 1992 to 1993:      Harvard School of Public Health  
                              Postgraduate programs  
                              Lecturer and course developer: Regression and ANOVA
- 1989 to 1990:      London School of Hygiene and Tropical Medicine  
                              MSc Medical Statistics  
                              Lecturer and course developer: Distribution-free Methods  
                              Lecturer and course developer: Bayesian Methods

Lecturer: Clinical Trials Methodology.

1988 to 1990:

City University, London  
BSc Statistics and BSc Actuarial Science  
Lecturer and course developer: Clinical Trials Methodology

1988 to 1989:

Royal College of Radiologists, London  
Fellowship qualification course  
Lecturer and course developer: Introductory Statistics &  
Clinical Trial Methodology

1986 to 1989:

Royal Free Hospital School of Medicine, London  
MB (Medicine)  
Lecturer: Introductory Statistics

1985 to 1986:

University of Kent at Canterbury  
MA Management Science  
Seminar tutor: Statistics and Operational Research

PhD Thesis Advisor:

Assistant PhD Thesis Advisor:

Postdoctoral Fellow Advisor:



**APPEARS THIS WAY  
ON ORIGINAL**

## **Publications**

### **Journals**

1. Grob JP, Grundy JE, Prentice HG, Griffiths PD, Hoffbrand AV, Hughes MD, Tate T, Wimperis JZ, Brenner MK. 'Immune donors can protect marrow-transplant recipients from severe cytomegalovirus infections'. *Lancet*. 1987;i:774-776.
2. Pocock SJ, Hughes MD, Lee RJ. 'Statistical problems in the reporting of clinical trials'. *New England Journal of Medicine*. 1987;317:426-432.
3. AIMS Trial Study Group. 'Effect of intravenous APSAC on mortality after acute myocardial infarction: preliminary report of a placebo-controlled clinical trial'. *Lancet*. 1988;i:545-549.
4. Hughes MD. 'A stochastic frontier cost function for residential child care provision'. *Journal of Applied Econometrics*. 1988;3:203-214.
5. Hughes MD, Pocock SJ. 'Stopping rules and estimation problems in clinical trials'. *Statistics in Medicine*. 1988;7:1231-1242.
6. Hughes MD. In discussion to: Begg CB, Berlin JA. 'Publication bias: a problem in interpreting medical data'. *Journal of the Royal Statistical Society Series A*. 1988;151:419-463.
7. Morreale M, Tsirigotis M, Hughes MD, Brumfitt W, McIntyre N, Burroughs AK. 'Significant bacteriuria has prognostic significance in primary biliary cirrhosis'. *Journal of Hepatology*. 1989;9:149-158.
8. Hughes MD. In discussion to: Jennison C, Turnbull BW. 'Interim analyses: the repeated confidence interval approach'. *Journal of the Royal Statistical Society, Series B*. 1989;51:305-362.
9. Pocock SJ, Hughes MD. 'Practical problems in interim analyses with particular regard to estimation'. *Controlled Clinical Trials*. 1989;10:209S-221S.
10. PACK claudication sub-study investigators. 'Randomized placebo-controlled, double-blind trial of ketanserin in claudicants: changes in claudication distance and ankle systolic pressure'. *Circulation*. 1989;80:1544-1548.
11. AIMS Trial Study Group. 'Long term effects of intravenous anistreplase (eminase) in acute myocardial infarction: final report of the AIMS study'. *Lancet*. 1990;335:427-431.

12. Pocock SJ, Hughes MD. 'Estimation issues in clinical trials and overviews'. *Statistics in Medicine*. 1990;9:657-671.
13. Burroughs AK, McCormick PA, Hughes MD, Sprengers D, D'Heygere F, McIntyre N. 'Randomized, double-blind, placebo-controlled trial of somatostatin for variceal bleeding: emergency control and prevention of early variceal rebleeding'. *Gastroenterology*. 1990;99:1388-1395.
14. SWIFT Trial Study Group. 'SWIFT trial of delayed elective intervention versus conservative treatment after thrombolysis with anistreplase in acute myocardial infarction'. *British Medical Journal*. 1991;302:555-560.
15. Hughes MD. 'Practical reporting of Bayesian analyses of clinical trials'. *Drug Information Journal*. 1991;25:381-393.
16. Hughes MD, Freedman LS, Pocock SJ. 'The impact of stopping rules on heterogeneity of results in overviews of clinical trials'. *Biometrics*. 1992;48:41-53.
17. Hughes MD, Pocock SJ. 'Within-subject diastolic blood pressure variability: implications for risk assessment and screening'. *Journal of Clinical Epidemiology*. 1992;45:985-998.
18. van Essen-Zandvliet EEM, Hughes MD, Waalkens HJ, Duiverman EJ, Pocock SJ, Kerrebijn KF and the Dutch Chronic Non-specific Lung Disease Group. 'Effects of 22 months treatment with inhaled corticosteroids and/or beta-2-agonists on lung function, airway responsiveness and symptoms in children with asthma'. *American Review of Respiratory Disease*. 1992;146:547-557.
19. Kerstjens HAM, Brand PLP, Hughes MD, Robinson NJ, Postma DS, Sluiter HJ, Bleecker ER, Dekhuijzen PNR, de Jong PM, Mengelers HJJ, Overbeek SE, Schoonbrood DFME and the Dutch Chronic Non-specific Lung Disease Study Group. 'A comparison of bronchodilator therapy with or without inhaled corticosteroid therapy in obstructive airways disease'. *New England Journal of Medicine*. 1992;327:1413-1419.
20. Hughes MD, Raskino CL, Pocock SJ, Biagini MR, Burroughs AK. 'Prediction of short-term survival with an application in primary biliary cirrhosis'. *Statistics in Medicine*. 1992;11:1731-1745.
21. Hughes MD. 'Stopping guidelines for clinical trials with multiple treatments'. *Statistics in Medicine*. 1993;12:901-915.
22. Hughes MD, van Essen-Zandvliet EEM, Kerstjens HAM. 'Issues in the design of long-term clinical trials in asthma'. *Drug Information Journal*. 1993;27:793-803.



23. Hughes MD. 'Reporting Bayesian analyses of clinical trials'. *Statistics in Medicine*. 1993;12:1651-1663.
24. Waalkens HJ, van Essen-Zandvliet EE, Hughes MD, Gerritsen J, Duiverman EJ, Knol K, Kerrebijn KF, the Dutch CNSLD Study Group. 'Cessation of long-term treatment with inhaled corticosteroid (Budesonide) in children with asthma results in deterioration'. *American Review of Respiratory Disease*. 1993;148:1252-1257.
25. Hughes MD. 'Regression dilution in the proportional hazards model'. *Biometrics*. 1993;49:1056-1066.
26. van Essen-Zandvliet EE, Hughes MD, Waalkens HJ, Duiverman EJ, Kerrebijn KF and the Dutch CNSLD Study Group. 'Remission of childhood asthma after long-term treatment with an inhaled corticosteroid (Budesonide): Can it be achieved?'. *European Respiratory Journal*. 1994;7:63-68.
27. Hughes MD, Stein DS, Gundacker HM, Valentine FT, Phair JP, Volberding PA. 'Within-subject variation in CD4 lymphocyte count in asymptomatic human immunodeficiency virus infection: implications for patient monitoring'. *Journal of Infectious Diseases*. 1994;169:28-36.
28. Hughes MD, Thompson SG, Pocock SJ. 'Optimal sequential screening guidelines for quantitative risk factors measured with error'. *Journal of the American Statistical Association*. 1995;90:19-26.
29. Lin H-M, Hughes MD. 'Use of historical marker data for assessing treatment effects in phase I/II trials when subject selection is determined by baseline marker level'. *Biometrics*. 1995;51:1053-1063.
30. Hughes MD, DeGruttola V, Welles SL. 'Evaluating surrogate markers'. *Journal of Acquired Immunodeficiency Syndromes and Human Retrovirology*. 1995;10:S1-S8.
31. Banks PA, Gerzof SG, Langevin RE, Silverman SG, Sica GT, Hughes MD. 'CT-guided aspiration of suspected pancreatic infection: bacteriology and clinical outcome'. *International Journal of Pancreatology*. 1995;18:265-270.
32. Jacobson MA, Gundacker H, Hughes MD, Fischl M, Volberding P. 'Zidovudine side effects as reported by black, Hispanic, and white/non-Hispanic patients with early HIV disease: Combined analysis of two multicenter placebo-controlled trials'. *Journal of Acquired Immunodeficiency Syndromes and Human Retrovirology*. 1996;11:45-52.
33. Banks PA, Carr-Locke DL, Slivka A, Van Dam J, Lichenstein DR, Hughes MD. 'Urinary trypsinogen activation peptides (TAP) are not increased in mild ERCP-induced pancreatitis'. *Pancreas*. 1996;12:294-297.

34. D'Aquila RT, Hughes MD, Johnson VA, Fischl MA, Sommadossi J, Liou S, Timpone J, Myers M, Basgoz N, Niu M, Hirsch MS and the National Institute of Allergy and Infectious Diseases AIDS Clinical Trials Group Protocol 241 Investigators. 'Nevirapine, zidovudine and didanosine compared with zidovudine and didanosine in patients with human immunodeficiency virus type 1 infection. A randomized, double-blind placebo-controlled trial'. *Annals of Internal Medicine*. 1996;124:1019-1030.
35. Lin H-M, Hughes MD. 'Analysis of uncontrolled treatment changes in HIV clinical trials'. *Statistics in Medicine*. 1996;15:2053-2067.
36. Hammer SM, Katzenstein DA, Hughes MD, Gundacker H, Blaschke TF, Schooley RT, Haubrich RH, Henry WK, Lederman MM, Phair JP, Niu M, Hirsch MS, Merigan TC, for the AIDS Clinical Trials Group Study 175 Study Team. 'A trial comparing nucleoside monotherapy with combination therapy in HIV-infected adults with CD4 cell counts from 200 to 500 per cubic millimeter'. *New England Journal of Medicine*. 1996;335:1081-1090.
37. Katzenstein DA, Hammer SM, Hughes MD, Gundacker H, Jackson JB, Fiscus S, Lathey J, Rasheed S, Elbeik T, Reichman R, Japour A, Merigan TC, Hirsch M. 'The relation of virologic and immunologic markers to clinical outcomes after nucleoside therapy in HIV-infected adults with 200 to 500 CD4 cells per cubic millimeter'. *New England Journal of Medicine*. 1996;335:1091-1098.
38. Hughes MD. 'Power considerations for clinical trials using multivariate time-to-event data'. *Statistics in Medicine*. 1997;16:865-882.
39. Hughes MD, Johnson VA, Hirsch MS, Bremer JW, Elbeik T, Erice A, Kuritzkes DR, Scott WA, Spector SA, Basgoz N, Fischl MA, D'Aquila RT for the ACTG 241 Protocol Virology Substudy Team. 'Monitoring plasma HIV-1 RNA levels in addition to CD4+ lymphocyte count improves assessment of antiretroviral therapeutic response'. *Annals of Internal Medicine*. 1997;126:929-938.
40. Lin H-M, Hughes MD. 'Adjusting for regression to the mean when variables are normally distributed.' *Statistical Methods in Medical Research*. 1997;6:129-146
41. Tenner S, Fernandez-del Castillo C, Warshaw A, Steinberg W, Hermon-Taylor J, Valenzuela JE, Hariri M, Hughes M, Banks PA. 'Urinary trypsinogen activation peptide (TAP) predicts severity in patients with acute pancreatitis'. *International Journal of Pancreatology*. 1997;21:105-110.
42. Daniels MJ, Hughes MD. 'Meta-analysis for the evaluation of potential surrogate markers'. *Statistics in Medicine*. 1997;16:1965-1982.

43. Hammer SM, Squires KE, Hughes MD, Grimes JM, Demeter LM, Currier JS, Eron JJ, Feinberg JE, Balfour HH, Deyton LR, Chodakewitz JA, Fischl MA. 'A controlled trial of two nucleoside analogues plus indinavir in persons with human immunodeficiency virus and CD4 cell counts of 200 per cubic millimeter or less'. *New England Journal of Medicine*. 1997;337:725-733.
44. Lin H-M, Hughes MD. 'Assessing the effects of interventions using longitudinal data with samples subject to selection.' *Biometrics*. 1997;53:924-936.
45. Ioannidis JPA, Bassett R, Hughes MD, Volberding PA, Sacks HS, Lau J. 'Predictors and impact of patients lost to follow-up in a long-term randomized trial of immediate versus deferred antiretroviral treatment'. *Journal of Acquired Immunodeficiency Syndromes and Human Retrovirology*. 1997;16:22-30.
46. Hutchison DSC, Hughes MD. (editorial) 'Alpha-1-antitrypsin replacement therapy: will its efficacy ever be proved?'. *European Respiratory Journal*. 1997;10:2091-2093.
47. Banks P, Hughes MD, Ferrante M, Noordhoek E, Ramagopal V, Slivka A. 'Does allopurinol reduce pain of chronic pancreatitis?' *The International Journal of Pancreatology*. 1997;22:171-6.
48. Tenner S, Sica G, Hughes M, Noordhoeck E, Feng S, Zinner M, Banks PA. 'Relationship of necrosis to organ failure in severe acute pancreatitis'. *Gastroenterology*. 1997;113:889-903.
49. Kramer EM, Peterson K, Rogers BL, Hughes MD. 'Intra-household allocation of energy intake among children under five years and their parents in rural Bangladesh.' *European Journal of Clinical Nutrition*. 1997;51:750-756.
50. Brown A, Hughes M, Tenner S, Banks PA. 'Does pancreatic enzyme supplementation reduce pain in patients with chronic pancreatitis: A meta-analysis'. *American Journal of Gastroenterology*. 1997;92:2032-2035.
51. Heller SJ, Noordhoek E, Tenner SM, Ramagopal V, Abramowitz M, Hughes M, Banks PA. 'Pleural effusion as a predictor of severity in acute pancreatitis'. *Pancreas*. 1997;15:222-225.
52. Raboud JM, Montaner JSG, Rae S, Kahn J, Hammer SM, Katzenstein DA, Pavia A, Dolin R, Hughes MD, Cross A, Beltangady M, Gatell J, Dunkle L, Smaldone L. 'Meta-analysis of five randomized controlled trials comparing continuation of zidovudine versus switching to didanosine in HIV-infected individuals'. *Antiviral Therapy*. 1997;2:237-247.

53. Marschner IC, Collier AC, Coombs RW, D'Aquila RT, DeGruttola V, Fischl MA, Hammer SM, Hughes MD, Johnson VA, Katzenstein DA, Richman DD, Smeaton LM, Spector S, Saag MS. 'Use of changes in plasma levels of human immunodeficiency virus type 1 RNA to assess the clinical benefits of antiretroviral therapy.' *Journal of Infectious Diseases*. 1998;177:40-47.
54. Lathey JL, Hughes MD, Fiscus SA, Pi T, Jackson JB, Rasheed S, Elbeik T, Reichman R, Japour A, D'Aquila R, Scott W, Griffith B, Hammer SM, Katzenstein DA for the AIDS Clinical Trials Group Protocol 175 Team. 'Variability and prognostic values of virologic and CD4 cell measures in HIV-1-infected patients with 200 to 500 CD4 cells per cubic millimeter (ACTG 175)'. *Journal of Infectious Diseases*. 1998;177:617-624.
55. Fiscus SA, Hughes MD, Pi T, Lathey JL, Katzenstein DA, Hammer SM for the AIDS Clinical Trials Group 175 Virology Team. 'Changes in virologic markers as predictors of CD4 cell decline and progression of disease in HIV-1 infected adults treated with nucleosides'. *Journal of Infectious Diseases*. 1998;177:625-633.
56. Rey D, Hughes M, Pi J-T, Winters M, Merigan TC, Katzenstein DA for the AIDS Clinical Trials Group 175 Virology Team. 'HIV-1 reverse transcriptase codon 215 mutation in plasma RNA: immunologic and virologic responses to zidovudine'. *Journal of Acquired Immune Deficiency Syndromes and Human Retrovirology*. 1998;17:203-208.
57. Babiker A, Hughes M, Darbyshire J. (editorial) 'The role of HIV-1 RNA as a surrogate marker for clinical outcome in clinical trials evaluating new anti-HIV therapies'. *International Antiviral News*. 1998; 6:10-11.
58. D'Aquila RT, Sutton L, Savara A, Hughes MD, Johnson VA for the NIAID AIDS Clinical Trials Group Protocol 241 Virology Team. 'CCR5/ccr5 heterozygosity: A selective pressure for the syncytium-inducing human immunodeficiency virus type 1 phenotype'. *Journal of Infectious Diseases*. 1998; 177:1549-53.
59. Hughes MD, Daniels MJ, Fischl MA, Kim S, Schooley RT. 'CD4 cell counts as a surrogate endpoint in HIV clinical trials: a meta-analysis of studies of the AIDS Clinical Trials Group'. *AIDS*. 1998;12:1823-1832.
60. DeGruttola V, Hughes M, Gilbert P, Phillips A. 'Trial design in the era of highly effective antiviral combination drug combinations for HIV infection'. *AIDS*. 1998;12 Suppl A:S149-156.

61. Albert JM, Ioannidis JPA, Reichelderfer P, Conway B, Coombs RW, Crane L, DeMasi R, Dixon DO, Flandre P, Hughes MD, Kalish L, Larntz K, Lin DY, Marschner I, Munoz A, Murray J, Neaton J, Pettinelli C, Rida W, Taylor JMG, Welles SL. 'Statistical issues for HIV surrogate endpoints: point/counterpoint'. *Statistics in Medicine*. 1998;17:2435-2462.
62. Simpson DM, Katzenstein DA, Hughes MD, Hammer SM, Williamson DL, Jiang Q, Pi J-T and the ACTG 175/801 Study Team. 'Neuromuscular function in HIV infection: analysis of a placebo-controlled combination antiretroviral trial'. *AIDS*. 1998;12:2425-2432.
63. Zhou X-J, Sheiner L, D'Aquila RT, Hughes MD, Hirsch MS, Fischl MA, Johnson VA, Myers M, Sommadossi J-P. 'Population pharmacokinetics of nevirapine, zidovudine and didanosine in human immunodeficiency virus-infected patients'. *Antimicrobial Agents and Chemotherapy*. 1999;43:121-128.
64. HIV Trialists' Collaborative Group [Hughes MD was member of Secretariat who took responsibility for the paper]. 'Zidovudine, didanosine, and zalcitabine in the treatment of HIV infection: meta-analyses of the randomised evidence'. *Lancet*. 1999;353:2014-2025.
65. Friedland GH, Pollard R, Griffith B, Hughes M, Morse G, Bassett R, Freimuth W, Demeter L, Connick E, Nevin T, Hirsch M, Fischl M for the ACTG 261 Team. 'Efficacy and safety of the delavirdine mesylate with zidovudine and didanosine compared with two-drug combinations of these agents in persons with HIV disease with CD4 counts 100 to 500 cells/mm<sup>3</sup> (ACTG 261)'. *Journal of Acquired Immunodeficiency Syndromes and Human Retrovirology*. 1999;21:281-292.
66. Mander AP, Hughes MD, Sharp SJ, Lamm CJ. 'Autoregressive models for describing nonlinear changes in biological parameters fitted using BUGS'. *Statistics in Medicine*. 1999;18:2709-2722.
67. Phanuphak P, Grayson ML, Sirivichayakul S, Suwanagool S, Ruxrungtham K, Hanvanich M, Ratanasuwan W, Ubolyam S, Hughes MD, Wanke CA, Hammer SM. 'A comparison of two dosing regimens of zidovudine in Thai adults with early symptomatic HIV infection'. *Australia and New Zealand Journal of Medicine*. 2000;30:11-20.
68. Kim S, Hughes MD, Hammer SM, Jackson JB, DeGruttola V, Katzenstein DA. 'Both serum HIV-1 RNA levels and CD4 lymphocyte counts predict clinical outcome in HIV-1 infected subjects with 200 to 500 CD4 cells per cubic millimeter'. *AIDS Research and Human Retroviruses*. 2000;16:645-653.

69. Hughes MD. 'Analysis and design issues for studies using censored biomarker measurements, with an example of viral load measurements in HIV clinical trials'. *Statistics in Medicine*. 2000;19:3171-3191.
70. Torres AM, Peterson KE, de Souza AC, Orav EJ, Hughes M, Chen LC. 'Association of diarrhoea and upper respiratory tract infections with weight and height gains in Bangladeshi children aged 5 to 11 years'. *Bulletin of the World Health Organization*. 2000;78:1316-1323.
71. Coakley E, Samore M, Gillis J, Hughes M, Hammer S. 'The values of quantitative serum HIV-1 RNA levels and CD4 cell counts for predicting survival time among HIV-positive individuals with CD4 counts of  $\leq 50 \times 10^6$  cells/l'. *AIDS*. 2000;14:1147-1153.
72. HIV Surrogate Marker Collaborative Group [Hughes MD was Project Director and Corresponding Author]. 'Human immunodeficiency virus type 1 (HIV-1) RNA level and CD4 count as prognostic markers and surrogate endpoints: a meta-analysis'. *AIDS Research and Human Retroviruses*. 2000;16:1123-1133.
73. Albrecht MA, Hughes MD, Liou SH, Katzenstein DA, Murphy R, Balfour HH, Para MF, Valdez H, Hammer SM, for the ACTG 303 Study Team. 'Effect of lamivudine in HIV-infected persons with prior exposure to zidovudine/didanosine or zidovudine/zalcitabine'. *AIDS Research and Human Retroviruses*. 2000;16:1337-1344.
74. Katzenstein DA, Hughes M, Albrecht M, Hammer S, Para M, Murphy R, Valdez H, Haubrich R, Liou S. 'Virologic and CD4+ cell responses to new nucleoside regimens. Switching to stavudine or adding lamivudine after prolonged zidovudine treatment of human immunodeficiency virus infection'. *AIDS Research and Human Retroviruses*. 2000;16:1031-1037.
75. Lindsey JC, Hughes MD, Moye J, McKinney RE, Cowles MK, Englund JA, Baker CJ, Burchett SK, Kline MW, Kovacs A. 'Treatment mediated changes in HIV-1 RNA and CD4 counts as predictors of growth failure, cognitive decline and survival in HIV-infected children'. *Journal of Infectious Diseases*. 2000;182:1385-1393.
76. Currier JS, Spino C, Grimes J, Wofsy CB, Katzenstein DA, Hughes MD, Hammer SM, Cotton DJ. 'Differences between women and men in adverse events and CD4+ responses to nucleoside analogue therapy for HIV infection'. *Journal of Acquired Immunodeficiency Syndromes and Human Retrovirology*. 2000;24:316-324.
77. Katzenstein DA, Hughes M, Albrecht M, Liou SH, Murphy R, Blafour H, Para M, Hammer S for the ACTG 302 Study Team. 'Virologic and CD4 cell response to zidovudine or zidovudine and lamivudine following didanosine treatment of human immunodeficiency virus infection'. *AIDS Research and Human Retroviruses*. 2001;17:203-210.

78. Shulman NS, Machekano RA, Shafer RW, Winters MA, Zolopa AR, Liou SH, Hughes M, Katzenstein DA for the ACTG 302 Study Team. 'Genotypic correlates of a virologic response to stavudine after zidovudine monotherapy'. *Journal of Acquired Immunodeficiency Syndromes and Human Retrovirology*. 2001;27:377-380.
79. Buchacz K, Cervia JS, Lindsey JC, Hughes MD, Seage GR, Dankner WM, Oleske JM, Moye J, for the Pediatric AIDS Clinical Trials Group 219 Study Team. 'Impact of protease inhibitor-containing combination antiretroviral therapies on height and weight growth in HIV-infected children. *Pediatrics*. 2001;108(4)e72 [URL: <http://www.peditrics.org/cgi/content/full/108/4/e72>].
80. Acosta EP, Zorrilla C, van Dyke R, Bardequez A, Smith E, Hughes M, Huang S, Pitt J, Watts H, Mofenson L and the Pediatric AIDS Clinical Trials Group 386 Protocol Team. 'Pharmacokinetics of saquinavir-SGC in HIV-infected pregnant women'. *HIV Clinical Trials*. 2001;2:460-465.
81. O'Quigley J, Hughes M, Fenton T. 'Dose-finding designs for HIV studies'. *Biometrics*. 2001;57:1018-1029.
82. Demeter LM, Hughes MD, Coombs RW, Jackson JB, Grimes JM, Bosch RJ, Fiscus SA, Spector SA, Squires KE, Fischl MA, Hammer SM. 'Predictors of virologic and clinical outcomes in HIV-1-infected patients receiving concurrent treatment with indinavir, zidovudine and lamivudine'. *Annals of Internal Medicine*. 2001;135:954-964.
83. Gortmaker SL, Hughes M, Cervia J, Brady M, Johnson GM, Seage GR, Song LY, Dankner WM, Oleske JM, for the Pediatric AIDS Clinical Trials Group Protocol 219 Team. 'Effect of combination therapy including protease inhibitors on mortality among children and adolescents infected with HIV-1'. *New England Journal of Medicine*. 2001;345:1522-1528.
84. Church JA, Cunningham C, Hughes M, Palumbo P, Mofenson LM, Delora P, Smith E, Wiznia A, Purdue L, Hawkins E, Sista P, for the PACTG P1005 Study Team. 'Safety and antiretroviral activity of chronic subcutaneous administration of T-20 in human immunodeficiency virus 1-infected children'. *Pediatric Infectious Disease Journal*. 2002;21:653-659.
85. Gaughan DM, Mofenson LM, Hughes MD, Seage GR, Ciupak GL, Oleske JM, for the Pediatric AIDS Clinical Trials Group Protocol 219 Team. 'Osteonecrosis of the hip (Legg-Calve-Perthes Disease) in human immunodeficiency virus-infected children'. *Pediatrics*. 2002;109(5)e74 [URL: <http://www.peditrics.org/cgi/content/full/109/5/e74>].
86. Brown A, Baillargeon J-D, Hughes MD, Banks PA. 'Can fluid resuscitation prevent pancreatic necrosis in severe acute pancreatitis?'. *Pancreatology*. 2002;2:104-107.

87. Perez A, Whang EE, Brooks DC, Moore FD, Hughes MD, Sica GT, Zinner MJ, Ashley SW, Banks PA. 'Is severity of necrotizing pancreatitis increased in extended and infected necrosis?'. *Pancreas*. 2002;25:229-233.
88. Gaughan D, Hughes MD, Seage GR, Selwyn PA, Carey VJ, Gortmaker SL, Oleske JM. 'The prevalence of pain in pediatric HIV/AIDS as reported by participants in the Pediatric Late Outcomes Study (PACTG 219)'. *Pediatrics*. 2002;109:1144-1152.
89. Demeter LM, Bosch RJ, Coombs RW, Fiscus S, Bremer J, Johnson VA, Erice A, Jackson JB, Spector SA, Squires KM, Fischl MA, Hughes MD, Hammer SM. 'Detection of replication-competent human immunodeficiency virus type 1 (HIV-1) in cultures from patients with levels HIV-1 RNA in plasma suppressed to less than 500 or 50 copies per milliliter'. *Journal of Clinical Microbiology*. 2002;40:2089-2094.
90. Tuomala RE, Shapiro DE, Mofenson LM, Bryson Y, Culnane M, Hughes MD, O'Sullivan MJ, Scott G, Stek AM, Wara D, Bulterys M. 'Antiretroviral therapy during pregnancy and the risk of an adverse outcome'. *New England Journal of Medicine*. 2002;346:1863-1870.
91. Shulman NS, Hughes MD, Winters MA, Shafer RW, Zolopa AR, Hellmann NS, Bates M, Whitcomb JH, Katzenstein DA. 'Subtle decreases in stavudine phenotypic susceptibility predict poor virologic response to stavudine monotherapy in zidovudine-experienced patients'. *Journal of Acquired Immune Deficiency Syndromes*. 2002;31:121-127.
92. Vandervoot J, Soetikno RM, Tham TC, Wong RC, Ferrari AP, Montes H, Roston AD, Slivka A, Lichtenstein DR, Ruymann FW, van Dam J, Hughes M, Carr-Locke DL. 'Risk factors for complications after performance of ERCP'. *Gastrointestinal Endoscopy*. 2002;56:652-656.
93. Hughes MD. 'Evaluating surrogate endpoints'. *Controlled Clinical Trials*. 2002;23:703-707.
94. Buchacz K, Rogol AD, Lindsey JC, Wilson CM, Hughes MD, Seage GR, Oleske JM, Rogers AS, for the Pediatric AIDS Clinical Trials Group 219 Study Team. Delayed onset of pubertal development in children and adolescents with perinatally acquired HIV infection. *Journal of Acquired Immune Deficiency Syndromes*. 2003;33:56-65.
95. Singh KK, Barroga CF, Hughes MD, Chen J, Raskino C, McKinney RE, Spector SA. 'Genetic influence of CCR5, CCR2 and SDF1 variants on HIV-1 related disease progression and neurological impairment in children with symptomatic HIV-1 infection'. *Journal of Infectious Diseases*. 2003. In press.



96. Wu H, Lathey J, Ruan P, Douglas SD, Spector SA, Lindsey J, Hughes MD, Rudy BJ, Flynn PM. 'Relationship of plasma HIV-1 RNA dynamics to baseline factors and virological responses to highly active antiretroviral therapy (HAART) in adolescents (aged 12-22 years) infected through risk behaviour'. *Journal of Infectious Diseases*. 2003. In press.

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### **Book contributions**

1. Bebbington AC, Davies BP, Charnley HM, Ferlie EB, Hughes MD, Twigg J. Resources. Needs and Outcomes in Community-based Care: A Comparative Study of Services for the Elderly. Gower: Aldershot, 1990.
2. Hughes MD, Pocock SJ. 'Estimation after stopping a clinical trial early.' In: Statistics in Medicine (eds. Dunstan F, Pickles J). Oxford University Press: Oxford, 1991.
3. Hughes MD, Pocock SJ. 'Interim monitoring of clinical trials.' In: AIDS Clinical Trials (eds. Finkelstein D, Schoenfeld D). Wiley: New York, 1995.
4. Hughes MD, DeGruttola V. 'Design of clinical trials of treatments for HIV infection.' In: Antiviral Agents and Human Viral Diseases (eds. Galasso GJ, Whitley RJ, Merigan TC). 4th edition. Lippincott-Raven Publishers, Philadelphia. 1997.
5. Hughes MD. 'Multiplicity in Clinical Trials.' In Encyclopaedia of Biostatistics (eds. Armitage P, Colton T). Wiley: Chichester, 1998.
6. Hughes MD. 'Multiplicity in Clinical Trials.' In Clinical Trials (eds. Redmond C, Colton T). Wiley: Chichester, To appear.

### **Books Reviewed**

1. Salsburg S. The Use of Restricted Significance Tests in Clinical Trials. Springer-Verlag: New York, 1992. Statistics in Medicine. 1994; 13:1598.
2. Bernardo JM, Smith AFM. Bayesian Theory. Wiley, Chichester. 1994. Statistics in Medicine. 1996; 15:2124-2125.

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ON ORIGINAL**